

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US05/012122

International filing date: 11 April 2005 (11.04.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/561,480
Filing date: 12 April 2004 (12.04.2004)

Date of receipt at the International Bureau: 16 September 2005 (16.09.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

1365423

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

September 07, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/561,480

FILING DATE: April 12, 2004

RELATED PCT APPLICATION NUMBER: PCT/US05/12122



Certified by

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office


Please type a plus sign (+) inside this box 

PTO/SB/16 (5-03)
Approved for use through 04/30/2003. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
STEVEN D. SCOTT J.		KIMMELL GERONDALE		12754 DEON PLACE, GRANADA HILLS, CA 91344-1001 12 RISERO DRIVE, MISSION VIEJO, CA 92692	
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
MULTI-SITE BLISTER INJECTION SYSTEM					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number		26822		 Place Customer Number Bar Code Label Here PATENT TRADEMARK OFFICE	
OR Type Customer Number here					
<input checked="" type="checkbox"/> Firm or Individual Name		WALTER A. HACKLER, Ph.D.			
Address		2372 S.E. BRISTOL STREET, SUITE B			
Address					
City		NEWPORT BEACH	State	CALIFORNIA	ZIP 92660-0755
Country		US	Telephone	(949) 851-5010	Fax (949) 752-1925
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification		Number of Pages		7	
<input checked="" type="checkbox"/> Drawing(s)		Number of Sheets		2	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76		<input type="checkbox"/> CD(s), Number			
		<input checked="" type="checkbox"/> Other (specify)		ASSIGNMENT; COVER SHEET	
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees				FILING FEE AMOUNT (\$)	
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:		08-0114		\$160.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME WALTER A. HACKLER

TELEPHONE

(949) 851-5010

Date

04/12/2004

REGISTRATION NO.

27,792

(if appropriate)

Docket Number:

3155P

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

P19LARGE/REV05

MULTI-SITE BLISTER INJECTION SYSTEM

The present invention is generally directed to the administration of a medicament and is more particularly
5 directed to a multi-site injection system for dermal delivery of a medicament.

SUMMARY OF THE INVENTION

10 A multi-site blister injection system in accordance with the present invention generally includes a carrier sheet including a plurality of medicament filled rupturable blister disposed on an inside surface thereof.

15 A plurality of needles extending from the outside of the carrier stream is provided with each needle being aligned with a corresponding blister and having a lumen for transport of the medicament into a stratum corneum of a user.

20 Each of the needles is positioned for traversing the carrier sheet and rupturing the corresponding blister.

A pressure plate is disposed on the carrier sheet inside surface for forcing a blister against the needles for causing
25 rupture thereof and forcing a medicament through the needle lumens.

In one embodiment of the present invention, the pressure plate is fixed to the carrier sheet and a foam pad is disposed

on the carrier sheet outside. Preferably, the foam pad covers the needles extending the carrier sheet outside and is penetrable by the needles.

5 The foam pad may be adhered to the pressure plate along a perimeter thereof for securing the carrier sheet between the foam pad and the pressure plate. Preferably, the medicament in accordance with the present invention comprises botulinum toxin.

10

BRIEF DESCRIPTION OF THE DRAWINGS

15 The advantages and features of the present invention will be better understood by the following description when considered in conjunction with the accompanying drawings in which:

20 Figure 1 is a perspective view of a multi-site blister injection system in accordance with the present invention generally showing a carrier sheet and a pressure plate disposed on an inside surface of the carrier sheet;

25 Figure 2 is an exploded perspective view of the system more clearly illustrating a carrier sheet with medicament filled blisters and a foam pad;

 Figure 3 is a cross sectional view of the embodiments shown in Figures 1 and 2 more clearly illustrating a plurality of needles extending from the carrier sheet, a plurality of

rupturable blisters filled with a medicament, such as botulinum toxin, along with the pressure plate positioned for forcing the blisters against corresponding needles for causing rupture thereof and forcing medicament through needle lumens;
5 and

Figure 4 is a cross sectional view similar to that shown in Figure 3 in which the pressure plate has been forced against the blisters and medicament is forced into the stratum
10 corneum of a users skin.

DETAILED DESCRIPTION

With reference to Figures 1 and 2, there is shown a
15 multi-site injection system 10 in accordance with the present invention showing a carrier sheet 12 along with a foam pad 14, see Figure 2. A pressure plate 16 is disposed on a carrier sheet inside surface 20 and the foam pad 14 may include an adhesive for holding the carrier sheet 12 against the pressure
20 plate 16.

With reference to Figure 3 and 4, the carrier sheet 12 may be of conventional design and include blisters 24 filled with a medicament 26 as well as a plurality of protruding
25 needles 30 extending from an outside surface 32 of the carrier sheet 12. Each of the needles which may be, for example, 28 gauge and having 2mm length and include lumens 36 for transport of medicament therethrough.

Each of the needles 30 is aligned with a corresponding blister 24 and each needle including a point 38 for rupturing of corresponding blisters 24.

5 As shown, the pressure plate preferably includes a plurality of berms 40 for providing enhanced pressure against blisters as the pressure plate 16 is forced against the blisters 24.

10 The foam pad 14 preferably has a depth equal to or slightly greater than the length of the needles 30 in order to prevent inadvertent contact with the needles before use.

15 In operation, as shown in Figure 4, when the pressure plate 16 is forced downwardly as indicated by the arrows 44, the needle points 38 are rupture the blisters 24 and continued pressure by the pressure plate 16 collapses the blisters 24 and forces medicament through the needle lumens 36 as indicated by the arrows 42.

20 This pressure also compresses the foam pad 14 as shown against a users skin 44 and into the stratum corneum 46. It should be appreciated that the drawings are not to scale but rather enlarged to illustrate the operation of the multi-site
25 injection system 10.

Although there has been hereinabove described a specific multi-site blister injection system in accordance with the present invention for the purpose of illustrating the manner

in which the invention may be used to advantage, it should be appreciated that the invention is not limited thereto. That is, the present invention may suitably comprise, consist of, or consist essentially of the recited elements. Further, the invention illustratively disclosed herein suitably may be practiced in the absence of any element which is not specifically disclosed herein. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art, should be considered to be within the scope of the present invention as defined in the appended claims.

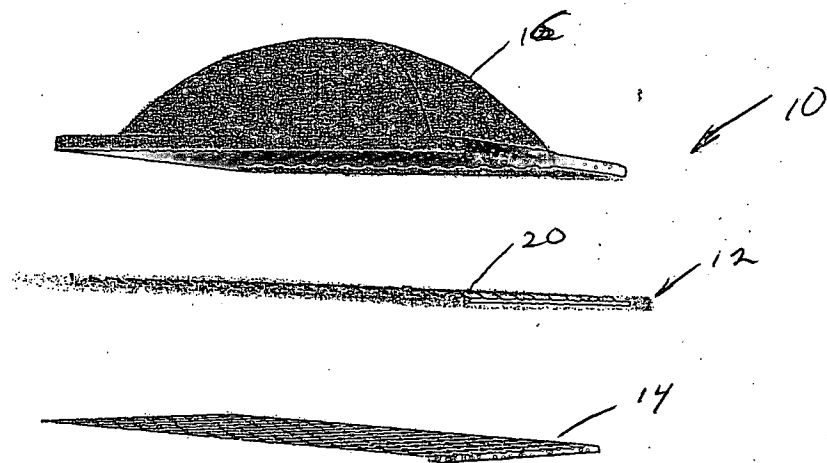
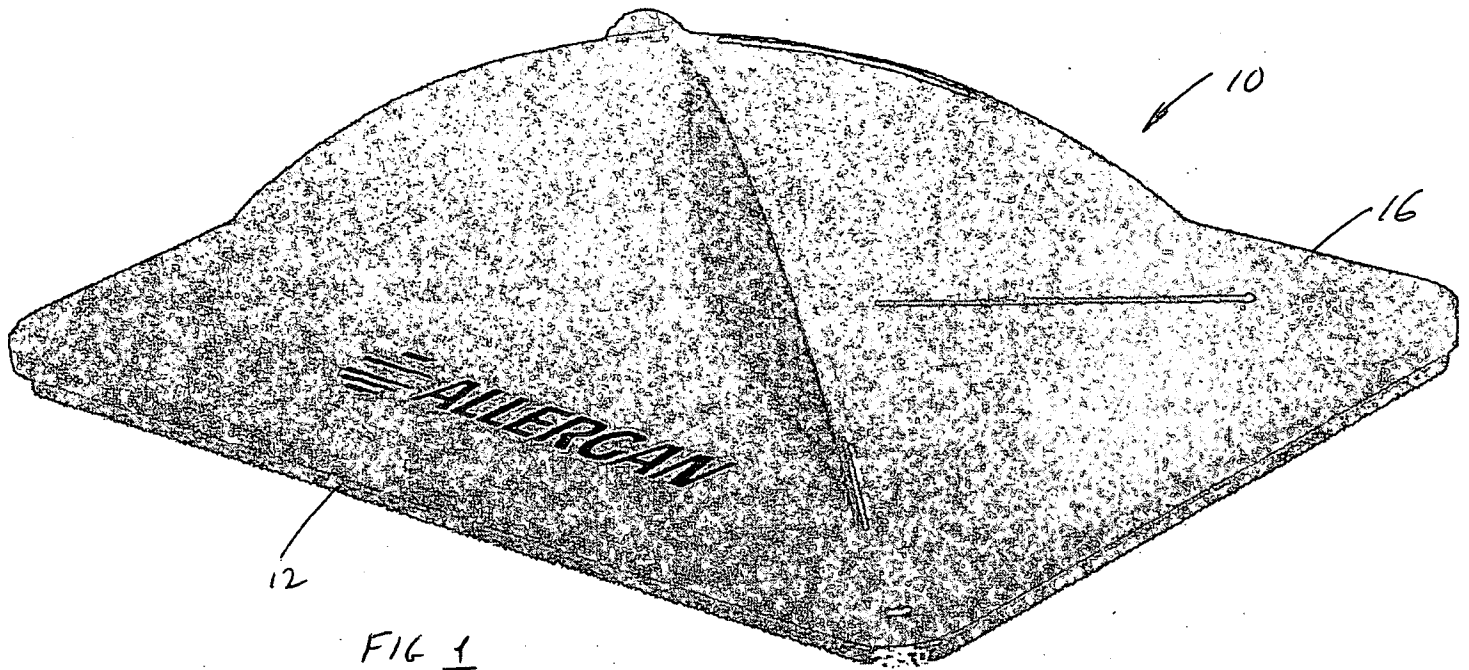
WHAT IS CLAIMED IS:

1. A multi-site injection system comprising:
 - a carrier sheet including a plurality of medicament
5 filled rupturable blisters disposed on an inside surface thereof;
 - a plurality of needles extending from an outside surface of said carrier sheet, each needle being aligned with a corresponding blister and having a lumen for transport of
10 the medicament into a stratum corneum of a user, each needle traversing said carrier sheet and positioned for rupturing the corresponding blister; and
 - a pressure plate disposed on the carrier sheet inside surface for forcing the blister against the needles for
15 causing rupture thereof and forcing the medicament through the needle lumens.
2. The system according to claim 1 wherein said pressure plate is fixed to said carrier sheet.
20
3. The system according to claim 2 further comprising a foam pad disposed on the carrier sheet outside.
4. The system according to claim 3 wherein said foam
25 pad covers the needle extending from the carrier sheet outside and is penetrable by said needle.
5. The system according to claim 5 wherein said foam pad is adhered to said pressure plate along a perimeter

3155

thereof for securing the carrier sheet between said foam pad and said pressure plate.

6. The system according to any one of claim 1-5 wherein
5 said medicament comprises botulinum toxin.



BEST AVAILABLE COPY

FIG 3

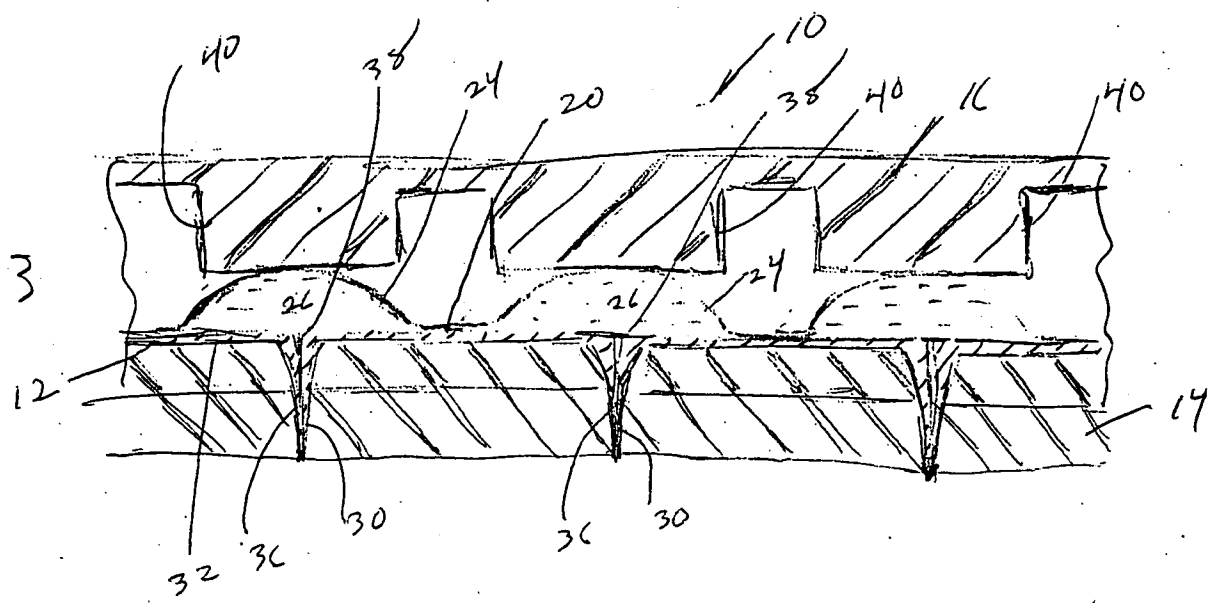


FIG 4

